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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,712	12/12/2000	D. Wade Walke	LEX-0109-USA	5587

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/735,712	WALKE ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment in Paper No. 20 filed on August 8, 20003 has been entered in full. Claims 1-8 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim rejection under 35 U.S.C. § 101

The rejection of claims 1-8 under 35 U.S.C. §101, as set forth in the previous Office Action (Paper No. 9, 12, & 18), remains. Claims 1-8 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility. The basis for this rejection is set forth in the previous Office Action (Paper No. 9, 12, & 18).

Beginning at page of 2 of the Applicants' response, Applicants argue that the amino acid sequence of SEQ ID NO: 2 of the present invention is identical to Accession No. Q9H3V2 (Exhibits B and C), which has been annotated as encoding "Membrane-spanning 4-domains subfamily A member 5. Applicants further submit that the expression of the sequences of the present invention was described in the specification as human testis cells and the activity of this protein is described in several publications

(Exhibit D), which demonstrate that the proteins of the present invention have function and utility that are both accepted by those skilled in the art.

This has been fully considered but is not deemed to be persuasive for the following reasons. First, while sharing sequence homology, SEQ ID NO: 2 of the present invention is NOT identical to Accession No. Q9H3V2 (see the sequence comparison shown in Exhibit C), as asserted by the Applicants. As indicated in the previous Office Action (Paper No. 9 & 12), the sequence homology alone does not render the present sequence a patentable utility. Secondly, the expression of the sequences of the present invention in human testis cells does not provide a specific and substantial utility because it fails to provide supporting evidence on the specific biological functions or the diagnostic/therapeutic value of the present sequences. Finally, the publications shown in the Exhibit D do not identify a specific biological function or any physiological significance for the present sequence; these studies are also based upon sequence analysis. As stated by Ishibashi et al., "The identification of this relatively large gene family in various tissues will allow the further elucidation of physiological significance of this gene family, that is currently unclear." (Gene, 264: 87-93, 2001, Exhibit D, Abstract). Therefore, the exhibits do not provide a specific and substantial utility for the present sequences.

At the third paragraph of page 3, Applicants continue to argue that the presently claimed molecules have been shown to encode, as asserted in the specification as filed, a human CD20 antigen-like molecule, membrane-spanning 4–domains subfamily A

member 5. Thus, the present situation directly tracks Example 10 of the Revised interim Utility Guidelines Training Materials.

This has been fully considered but is not deemed to be persuasive for the reasons set forth above and in Paper No. 9 & 12. Furthermore, in Example 10 of the Revised interim Utility Guidelines Training Materials, the claimed nucleic acid sequence has a well established utility because the high sequence homology can place the protein encoded by the claimed nucleic acid sequence in a DNA ligase family, whereas ligases have a well established use in ligating DNA. It is not the case here.

Beginning of page 4, Applicants argue that the present nucleotide sequence has a specific utility in determining the genomic structure of the corresponding human chromosome and provides biologically validated empirical data. This has been fully considered but is not deemed to be persuasive for the reasons set forth in Paper No. 12 (bottom of page 5-top of page 6).

Beginning at the 2nd paragraph of page 5, Applicants argue that an additional utility includes the use of the presently claimed polynucleotides on DNA chips. Applicants submit that knowledge of the exact function or role of the presently claimed sequence is not required to track expression patterns using a DNA chip. Such "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents and industrial success.

This has been fully considered but is not deemed to be persuasive for the following reasons. First, the Examiner notes that a gene chip is a customized device in biomedicine that allows researchers to detect, simultaneously, the presence and activity patterns of tens of thousands of DNA sequences in pieces of genetic material. A micro array can be used by researchers to describe the genetic malfunction associated with a disease, detect the presence of the disease in a particular patient, calculate a patient's genetic predisposition to that disease or identify the medicines likely to be most effective in treating a particular patient with the disease.

The specification fails to establish that the nucleic acid sequences are expressed at altered levels or forms in a specific diseased tissue as compared with the corresponding healthy tissue. If the nucleic acid sequences were in a microarray and a compound caused decreased expression of the claimed nucleic acids, what would that mean to the skilled artisan? Is it a potential drug, or would administering the compound be likely to acerbate an unspecified disease? If it had been disclosed that the nucleic acid sequences are expressed at a higher level in a particular diseased tissue as compared with the corresponding healthy tissue, the skilled artisan would know that a compound that decreased expression of the nucleic acid molecules is a good drug candidate that targets the disease. It is not the case here.

Furthermore, the nucleic acid sequences may very well be expressed at equivalent levels in healthy tissues. If it were the case, then the compound would not be a good drug candidate. The nucleic acid sequences may also very well be expressed at a

lower level in a particular diseased tissue as compared to the corresponding healthy tissue. Then a compound that decreased expression of the claimed polynucleotides would *not* be a good potential drug. Evidence of a differential expression might serve as a basis for use of nucleic acid sequences as a diagnostic for a disease. However, in the absence of any disclosed relationship between the nucleic acid molecules (or proteins encoded by the nucleic acids) and any diseases or disorders, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696. Thus, the disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Finally, the issued U.S. Patents related to DNA chips merely show that the technology itself is important and useful; they do not show that claimed invention has a patentable utility. Industrial success is not a standard for utility requirement. There is no doubt that a gene chip (or DNA chips) is a valuable tool in gene expression monitoring and drug discovery. However, the claims are not drawn to the technique, rather to nucleic acids which have not been disclosed as being associated with any particular diseases. Any such nucleic acid molecules could be added to a micro array. The use of the claimed uncharacterized nucleic acid molecules in such studies would have provided no more valuable information than the use of any other unidentified nucleic acids. Thus, this asserted utility is not specific. Determining the relationship between the claimed nucleic

acid molecules and any specific diseases or disorders would require significant further research. Therefore, this asserted utility is also not substantial.

Beginning at the bottom of page 6, Applicants challenges the legality of the Patent Examination Utility Guidelines and the validity of issued US patents. It is noted that an Examiner has no authority to comment on the legality of the Guidelines and the validity of US Patents.

Finally at page 7, Applicants summarize their arguments and submit that the presently claimed sequence molecules have a substantial, specific, credible and well-established utility, the rejection of the claims under 35 U.S.C. § 101 has been overcome. The Examiner believes that the rejections should be sustained for the reasons set forth above.

In summary, the specification fails to provide a specific, substantial, and credible utility, or a well-established utility for the claimed invention.

Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph

The rejection of claims 1-8 under 35 U.S.C. §112, 1st Paragraph, as set forth in the previous Office Action (Paper No. 9, 12, and 18), remains.

Claims 1-8 are rejected under 35 U. S. C. § 112, 1st paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility,

or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth in the previous Office Action (Paper No. 9, 12, and & 18).

Applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for the reasons set forth above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
October 20, 2003

Gary L Kunz

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SUPERVISORY PATENT EXAMINER
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